DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2015

Captiva Spine, Incorporated
% Rich Jansen, Pharm. D
Regulatory Consultant
Silver Pine Consulting, LLC
13540 Guide Avenue
Apple Valley, Minnesota 55124

Re: K141332
Trade/Device Name: Captiva Spine SmartLOX Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: May 14, 2015
Received: May 15, 2015

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141332

Device Name
Captiva Spine SmartLOX Cervical Plate System

Indications for Use *(Describe)*
The Captiva Spine SmartLOX Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudoarthrosis or failed previous fusion. WARNING: The Captiva Spine SmartLOX Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date Prepared: May 14, 2015
Submitter Contact: Dale Mitchell
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Regulatory Contact: Rich Jansen, Pharm. D.
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Trade Name: Captiva Spine SmartLOX Cervical Plate System
Product Class: Class II
Classification: 888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Codes: KWQ
Panel Code: 87

Reason for this Submission: This Traditional 510(k) involves several changes to the previously cleared Cervical Plate System that allow for:

1. Modifications to cervical plate configurations
2. Modifications to rail lock configuration
3. Modifications to screw design configurations
4. New or modified instrumentation

Indications for Use:
The Captiva Spine SmartLOX Cervical Plate System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudoarthrosis or failed previous fusion. WARNING: The Captiva Spine SmartLOX Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Device Descriptions:
The Captiva Spine SmartLOX Cervical Plate system is intended for anterior screw fixation of the cervical spine. This system has been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and

radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudoarthrosis or failed previous fusion.

The Captiva Spine SmartLOX Cervical Plate System includes plates, screws, and a screw-retaining rail lock. The plates are available in a variety of lengths ranging from 20 to 110mm. Screws are offered in two diameters, a primary screw diameter and a rescue diameter. Primary screws are available in self-drilling, and both screw diameters are available in fixed and variable versions. Screw lengths range from 12 to 18mm in 2mm increments. The rails are assembled with the plate during the manufacturing process and their configuration varies with the plate length.

The Captiva Spine SmartLOX Cervical Plate System is supplied with the instrumentation necessary for implantation of the system. The Captiva Spine SmartLOX Cervical Plate System is for single use only.

Predicate Device(s):
The Captiva Spine SmartLOX Cervical Plate System is substantially equivalent to the previously cleared Precision Surgery Ltd. Fixed, Variable and Corpectomy Cervical Plate System found in both K032815 and K073708 (primary predicate) and Medtronic Sofamor Danek Orion Anterior Cervical Plate System cleared per K042499.

Performance Standards:
Captiva Spine SmartLOX Cervical Plate System was evaluated to demonstrate equivalence to the predicate device. The worst-case implants were previously tested and performed equally to or better than the predicate devices in static compression, static torsion and dynamic compression in accordance with ASMT F1717. Engineering analysis of the proposed design changes included Design Failure Modes and Effect Analysis (FMEA) as well as a tabulated comparison between Captiva Spine SmartLOX Cervical Plate System and the predicates. The comparative analysis included product code, indications for use, material and screw/plate dimensions. Based on the completed engineering analysis's it was determined that the modified implants have the same indication for use, are within the previously cleared device size ranges, made of the same materials and do not represent new worst case for mechanical testing and therefore no new performance testing was required. No clinical or animal studies were performed.

Corrosion susceptibility was tested per ASTM F2129-08 and Galvanic Corrosion was tested per ASTM F3044-14.

Substantial Equivalence:
Captiva Spine concludes that there are no significant differences between the Captiva Spine SmartLOX Cervical Plate System and the other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in intended use, indications for use, fundamental technology including design, materials, sterility and operational principles.